REMARKS

In this 1st Official Action, the Patent Examiners of record have taken all of the following actions:

(i) The Examiners have pointed out that the listing of references in the Specification text is not an Information Disclosure Statement in accordance with the provisions of 37 CFR 1.98(b).

(ii) The Examiners have rejected original claims 1-8 respectively under 35 USC 112, 2nd paragraph as being indefinite in language for specifically stated reasons.

(iii) The Examiners have rejected claims 1-8 respectively under 35 USC 102(b) as being anticipated by the Vaillancourt '138 patent [U.S. Patent No. 5,591,138].

In response, applicants have taken the following actions:

(α) Applicants have canceled original dependent claims 4 and 5 respectively, without prejudice.

(β) Applicants have amended original claims 1-3 and 6-8 respectively.

Accordingly, via the present cancellations and amendments to the originally presented claims, as well as by the discussion presented hereinafter, applicants believe they have overcome and obviated each basis for rejection stated by the Examiners in the instant 1st Official Action.

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I. Applicants' Intentions And Goals

Applicant and their undersigned attorney wish to state their intentions clearly to the Examiner of record. It is our express desire and purpose to advance the prosecution of the instant application on the merits, and not to delay or hinder its progress unnecessarily.

To achieve this goal, applicant has therefore canceled original claims 4 and 5, without prejudice; and substantively amended original claims 1-3 and 6-8 respectively of the application. Via these claim cancellations and amendments, applicant has markedly altered the definition of the subject matter as a whole comprising the instant invention; and also generated an amended set of claims which clearly define and particularly delineate the present invention as allowable subject matter having substantial patentable merit.

Concomitant with the instant claim cancellations and claim amendments, applicant will also directly address and summarily review each basis for rejection stated by the Examiners in the instant Official Action.

II. The Examiners' Remarks Concerning The Listing Of References

The Examiners have pointed out that the listing of references in the Specification text is not an Information Disclosure Statement in accordance with the provisions of 37 CFR 1.98(b). In reply, applicant and his undersigned attorney agree with the Examiners' stated view - in so far as it

goes. Nevertheless, some explanation appears necessary to place the Examiners' remarks in proper context.

Initially, applicant's undersigned attorney respectfully maintains that more than one particular mode and manner is available to the applicant for disclosing specific knowledge and/or detailed information relevant for patent prosecution purposes to the Patent Examiners. One specific means for the presentation of such knowledge and information is via the submission of an Information Disclosure Statement, in accordance with the provisions of 37 CFR 1.98(b). However, the procedure recited by 37 CFR 1.97 and 1.98 is not the sole or exclusive means by which a meaningful disclosure of relevant information may be lawfully made. To the contrary, a range of alternative modes and manners for providing information material to the prosecution of a U.S. patent application have long existed and are frequently employed in lieu of submitting an Information Disclosure Statement as such.

Second, applicants undersigned attorney respectfully submits that the listing of references presented at pages 2-3 of the Specification is part of the "Background Of The Invention" portion of the descriptive text; and constitutes one well established and long accepted means of legally complying with and factually satisfying applicant's dual obligations for a disclosure of material information and true candor, as required by 35 USC 1.56. It is useful also to recall that the requirements of 35 USC 1.56 are compulsory, while the procedure recited by 37 CFR 1.97 and 1.98 is merely

an optional procedure available to the applicant to use or not, as he sees fit.

Third, by providing this overt listing of relevant patents as part of the written description as to the current state of knowledge and developments within the technical field, the Specification text provides a beneficial service to the reader; informs the reader about related facts and publications; and provides a perspective of what facts the ordinarily skilled practitioner in this art considers important or noteworthy. Thus, so long as any person takes the time and effort to read what is actually written at pages 2-3 of the Specification text, that person cannot honestly state that he has not been well informed about relevant knowledge and material developments pertinent to the technical field.

Lastly, the Examiners' major point is also fully recognized and formally acknowledged. As the Examiners have stated "...unless the references have been cited by the examiner on form PTO-892, they have not been considered." Clearly, the Examiners have found other patent references which they deem to be of greater interest than those identified within the Specification text; and, as noted, these considered references have in fact been listed on form PTO-982 enclosed as part of the instant Official Action. Applicant and his undersigned attorney formally accept the current listing of references on form PTO-982 as only those publications actually considered by the Examiners.

III. The Rejection Under 35 USC 112, 2nd Paragraph

The Examiners have rejected original claims 1-8 respectively as being indefinite in language for failing to make clearly understood what applicant regards as the invention. The crux of the rejection basis centers on the use of allegedly indefinite terms such as "predetermined" and "prechosen" within the recited phrases; and the effect of these allegedly indefinite terms upon the words "dimensions", "configurations", and "aligned positions".

In response, the language of all the presently pending claims has been carefully amended to eliminate any vagueness of wording and to clarify the recitation of essential elements in the invention. Amended independent claims 1 and 2 respectively, as mirrored by amended independent claims 7 and 8 respectively, reveal the extent of these changes; and the present claim amendments have introduced clearly understood and unambiguous substitutes into the claim language in place of the original indefinite terms. In this manner, all the presently pending amended claims define applicant's invention in particularly pointed and distinctly focused words.

Furthermore, as regards the language of the presently amended claims as a whole, applicant respectfully submits that these pending claims do, in fact, set out and circumscribe a particular area or subject matter with a reasonable degree of precision and particularity. Applicant notes that it is here where the meaning of the language employed to define the invention is determined; not in a vacuum, but always with regard to the teachings of the

technical field and within the particular use or application disclosed by the Specification as it is understood and interpreted by one of ordinary skill in the pertinent art.

Applicant also affirms that each of the terms used in amended claims 1-3 and 6-8 respectively is well understood; and is not subject to numerous definitions and interpretations. Moreover, the recited language for each of these amended claims is explicit and clearly stated; and sets forth and circumscribes the particular subject matter area with the requisite reasonable degree of precision and particularity.

For these reasons, applicant respectfully submits that amended claims 1-3 and 6-8 respectively satisfy the requirements of precision, clarity and particularity required by the 2nd paragraph of 35 USC 112. Accordingly, applicant respectfully requests that the Examiners reconsider their stated position and withdraw this ground of rejection against the presently amended claims.

IV. The Rejection Under 35 USC 102(b)

The Examiners have rejected original claims 1-8 under 35 USC 102(b) as being anticipated by the Vaillancourt '138 patent reference [U.S. patent No. 5,591,138]. The Examiners have clearly presented their views and positions in support of this single rejection basis. Accordingly, it is therefore useful to summarize what a rejection based on anticipation legally requires.

A. Anticipation As A Legal Basis For Rejection:

As a matter of long established law, anticipation under 35 USC 102(b) requires exact identity of the claimed article within a conventionally known device or apparatus existing previously in the prior art. Each required element or essential component of the claimed article of manufacture (including each specific feature and limitation defining the entity as a whole) must be described or embodied, directly or indirectly, within a single reference. Moreover, the single prior art reference of record must describe the claimed subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art; and that such existence would be recognized by persons of ordinary skill in the field of the invention [In re Spada, 15 USPQ2d 1655 at 1657 (Fed. Cir. 1990)].

Also, in deciding the issue of anticipation, the Examiners must identify each requisite element and limitation recited within applicant's claims; determine their meaning in light of the description provided by the Specification; and identify the existence and presence for each of the corresponding elements and limitations within the disclosure of the allegedly anticipating reference [Scripts Clinical and Research Foundation vs. Genetech Inc., 18 USPQ2d 1001 (Fed. Cir. 1991); Glaverbel Society Anonyme vs. Northlake Marketing and Supply Inc., 35 USPQ2d 1496 (Fed. Cir. 1995)].

In addition, although not yet employed by the Examiners as a basis for rejection, it is deemed useful here also to identify the proper legal basis and standard for determining obviousness under 35 USC 103(a). Where applicant's claimed subject matter could be rejected as obvious in view of a single prior art reference (or a combination of two or more different references), a proper analysis must consider *inter alia* two factors: (I) whether the prior art of record would have suggested to those of ordinary skill in the art that they should make the claimed article; and (ii) whether the prior art would also have revealed that in so making, those of ordinary skill would have a reasonable expectation of success [In re Dow Chemical Company, 5 USPQ2d 1529 (Fed. Cir. 1988)]. Both the suggestion and the reasonable expectation of success must be found directly within the text of the prior art reference(s) itself and cannot be derived or extrapolated from applicant's disclosure [In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991)].

In addition, the same inquiry must be carried out in the context of a purported "obvious modification" of the prior art information. The mere fact that the prior art might be modified in any proposed manner does not make that modification obvious unless and until the prior art overtly suggested the desirability of the modification [In re Fritch, 23 USPQ2d 1780 (Fed. Cir. 1992) and the references cited therein].

Applicant therefore respectively submits that the Examiners views and conclusions as stated in the instant Official Action do not provide an

adequate basis for rejection against the invention defined by the presently pending amended claims. A review of the factual content disclosed by the single cited and applied prior art reference, the Vaillancourt '138 patent, will reveal the substantive errors in the Examiners' position.

B. The Factual Content Of The Vaillancourt '138 Patent:

1. The Vaillancourt invention is an improved needle assembly which provides a protective sheath for shielding a hypodermic needle and which uses a simple arrangement for locking the protective sheath into an extended protecting position [see Column 1, lines 1-5 and lines 57-67].

2. As shown by Figs. 1 and 6 of the Vaillancourt reference, the protected needle assembly must comprise not less than three requisite and essential components: a discontinuous housing component (11), a distinct rigid tube component (13), and a discrete sheath component (17). As disclosed by the reference, the housing (11) is employed for the mounting of a syringe or other needle structure [see Column 5, lines 61-66]; the rigid tube (13) is of cylindrical shape and is used to grasp the assembly [see Column 5, lines 66-67; and Column 6, lines 1-2]; and the sheath (17) is telescopically mounted within the tube (13) and is disposed around the needle in a protective relationship [see Column 6, lines 5-8].

3. The sheath component (17) in the Vaillancourt assembly is expressly required to include and provide several specific features and

attributes: (α) The sheath (17) has a septum (18) mounted at the front end of the sheath to seal the needle completely within the spatial interior of the sheath [see Column 6, lines 7-10]; (β) the sheath (17) is movable longitudinally over the tube (13) between an extended position covering the needle and a retracted position exposing the needle [see Column 6, lines 10–14]; and (δ) the sheath (17) includes at least one projection on the exterior of the sheath which is received within a guide slot in the rigid tube (13) [see Column 6, lines 29-31].

4. Equally important, the rigid tube component (13) in the Vaillancourt assembly must also demonstrate and present particular structural characteristics and properties. These include: (γ) a guide slot (22) which includes a circumferentially directed slot portion (23) for receiving the projection of the sheath when the sheath is in an extended position; (ε) a longitudinally directed slot portion (24); and (ζ) a V-shaped, inclined slot portion (25) at the proximal end of the tube which retains the projection of the sheath when the sheath is in a retracted position [see Column 6, lines 29-39].

5. The Vaillancourt reference also expressly teaches what the working relationship is among the three essential component parts of the needle assembly. When the projection (21) on the sheath (17) lies within the circumferential slot portion (23) of the rigid tube (13), the sheath (17) cannot be moved from the extended position. Thus, in order to use the

needle assembly, the face of the septum (18) of the sheath (17) is brought against the skin of the patient; and the rigid tube (13) is rotated slightly such that the projection (18) becomes displaced into and moves within the longitudinally disposed slot portion (24) of the guide slot (22). The continued pressure on the housing (11) causes the rigid tube (13) to slide telescopically forward over the sheath (17), and concomitantly causes the needle to pierce through the septum (18) and enter into the patient.

Subsequently, when the projection (21) reaches the end of the longitudinally disposed slot portion (24), the pressure on the assembly is released. However, the residual stress causes the sheath (17) to rotate again within the rigid tube (13), thereby causing the projection (21) to move into the V-shaped inclined slot portion (25) of the guide slot (22). This second sheath rotation and overt movement of the projection (21) into the V-shaped inclined slot portion (25) serves to lock the sheath (17) in the retracted position [see Column 6, lines 40-60].

This factual summary accurately presents the sum and substance of the Vaillancourt '138 patent reference.

C. Some Major Differences Of Applicant's Claimed Invention:

Applicant respectfully submits and maintains that there are many major differences marked distinctions between the instant invention defined by the presently amended claims and the subject matter disclosed by the Vaillancourt '138 patent reference. Among them are the following:

1. The Vaillancort '138 patent discloses and defines a protected needle assembly to prevent needle sticks. In contradistinction, the present invention describes and claims an on-demand needle retaining and locking mechanism in an intravenous needle-catheter assembly. Although each of the two purposes and goals are related, they are not similar or identical.

2. The Vaillancort '138 patent requires not less than three minimal component parts: a discontinuous housing component, a distinct rigid tube component, and a discrete sheath component. In contrast, the present inventions requires only two essential parts: an on-demand needle safety container; and a needle housing unit.

3. The Vaillancort '138 patent demands that the sheath component include and provide several specific protective features: a septum mounted at the front end of the sheath to seal the needle completely within the spatial interior of the sheath; a sheath which can be moved longitudinally over the rigid tube between an extended position (which covers the needle) and a retracted position (which exposes the needle); and at least one projection disposed upon the exterior of the sheath, which is to be received within a

guide slot in the rigid tube. Notably, applicant's claimed invention does not require any such features at all.

4. The Vaillancort '138 patent also calls for the rigid tube in the assembly to present a guide slot having particular structures and characteristics in order to have a functional locking mechanism: a circumferentially directed slot portion to receive the projection of the sheath, when the sheath is in the extended position; a longitudinally directed slot portion; and a V-shaped, inclined slot portion at the proximal end of the tube, to retain the projection of the sheath when the sheath is in the retracted position. Clearly, applicant's claimed invention does not require any such structures as part of its operative locking mechanism.

5. The Vaillancort '138 patent employs a singular working relationship among its three requisite component parts to place the assembly into a locked position. It will be recognized and appreciated in particular that two separate and individual rotations must be performed: First, the rigid tube must be rotated initially in order to cause the projection of the sheath to enter into the longitudinally disposed slot portion. Second, the sheath must be rotated subsequently in order that the projection then be moved into the V-shaped inclined slot portion. Thus, it is only by performing two different and distinct rotations in sequence that the sheath can become locked in the retracted position. This overt need for two rotations for the locking mechanism in the Vaillancort assembly is wholly different from the single

rotation requirement operative for applicant's claimed invention.

6. Applicant's claimed invention employs and utilizes an entirely unique and radically different locking structure in comparison to that presented by the Vaillancort '138 patent. As presently claimed, the locking structure comprises two entities: a sized solid tab member disposed on and extending from the exterior of the needle-safety container; and a configured spool section present as part of a needle housing, is alignable at will with the tab member, and is able to engage, retain and disengage the tab member on-demand. Neither of these unique inter-locking structural elements are shown or suggested, directly or indirectly, by the disclosure of the Vaillancort reference.

D. The Erroneous Conclusions Of The Examiners:

As a consequence of the factual review for the Vaillancort '138 patent and its comparison with the presently amended claims of the instant invention, applicant respectfully affirms that he has demonstrated and revealed that the views and conclusions stated by the Examiners concerning the issue of anticipation are mistaken and erroneous. Clearly, many major differences and distinctions exist between the disclosure of the Vaillancort '138 patent and the presently claimed invention.

Applicant therefore respectfully submits that the Examiners have not properly considered or appreciated the limited purpose, narrow informational

content, and particular structural and operation requirements for the assembly disclosed by the Vaillancort reference; and have unfortunately overlooked the restricted scope and constrained value of the assembly which is the subject matter disclosed by the cited and applied reference. It will be recognized that applicant has made considerable effort to identify the pertinent factual differences and distinctions via his summary of the '138 patent.

Moreover, applicants maintain that the Examiners have unfortunately wrongly chosen to extrapolate only certain items and specified details from the totality of information disclosed by the Vaillancort '138 patent; and have regrettably misapplied the ostensible value of these extrapolated items, particularly as regards the structural elements and particular limitations now required by the presently amended claims.

Applicant therefore affirms that the information content and value disclosed and/or implied by the Vaillancort '138 patent of record does not teach or suggest applicant's claimed subject matter with sufficient clarity or detail to establish that the instant invention existed in the prior art; and denies that any such alleged existence could or would be recognized by persons of ordinary skill in the art, given knowledge of the Vaillancort '138 patent reference.

Equally important, applicant also maintains that the Vaillancort '138 patent of record can not suggest to those of ordinary skill in the relevant

technical field that they should make applicant's claimed apparatus or utilize applicant's claimed invention for its intended purposes; nor does the '138 patent reveal or imply that, if one attempted to make or practice applicant's presently claimed invention, those of ordinary skill would have any reasonable expectation for success.

For all these reasons, applicant believes that the Examiners have unknowing committed prejudicial factual and legal errors in the evaluation and stated conclusions. Applicant therefore respectfully submits that each and every amended claim now pending satisfies the novelty requirements of 35 USC 102(b), as well as the non-obvious requirement of 35 USC 103(a). Accordingly, applicants respectfully request that the Examiners reconsider their stated conclusion and withdraw this ground of rejection against the presently pending claims.

V. Summary Of Applicant's Response

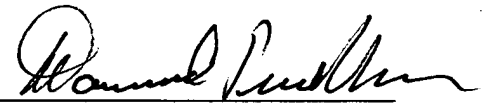
In sum, applicant has addressed each basis of rejection stated in the 1st Official Action forthrightly and objectively. In applicant's view, each relevant question or issue has been addressed and resolved completely. For these reasons, applicant respectfully submits and affirms that each of presently pending claims 1-3 and 6-8, as amended herein, are therefore allowable.

In view of the above discussion and detailed review, applicant believes that this application is now in condition for allowance and reconsideration is respectfully requested. The Examiners are invited to call applicant's undersigned attorney should they feel that such a telephone call would further the prosecution of the present application.

Respectfully submitted,

ROBERT M. BRUSTOWICZ

Date: Feb. 28, 2006

By: 

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